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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
2000 GALLOPING HILL ROAD
KENILWORTH, NJ 07033-0530

EXAMINER	
ALSTRUM ACEVEDO, JAMES HENRY	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 10/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/646,298	SHARPE ET AL.	
	Examiner	Art Unit	
	James H. Alstrum-Acevedo	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/ 6/04 & 10/14/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

SDO

DETAILED ACTION

Claims 1-20 are pending.

Specification

The disclosure is objected to because of the following informalities: the in-line chemical formula for the propellant HFA 227 on page 3, line 6, also known as HFC 227 or 1,1,1,2,3,3,3 heptafluoropropane, seems to have a typographical mistake, wherein one of the carbon atoms is represented by the letter "A" instead of the appropriate symbol, letter "C." The correct in-line chemical formula should read "CF_3CHFCH_3."

Appropriate correction is required.

The use of the trademarks TURBULA® mixer (pg 10, line 4) and AutoDose POWDERNIUM™ (pg 11, line 14) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially" in claim 1 is a relative term, which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The word "substantially" is used to describe the degree to which the formulations of the instant invention are free of a carrier. Because "substantially" implies a degree a standard or an unambiguous definition for the meaning of "substantially free of a carrier" is required to allow a person of ordinary skill in the art to clearly understand the meaning intended by the Applicant.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The phrase "free of a carrier" in claims 1 is used by the claim to mean "a formulation lacking an inert substance – the carrier- in which or on which the active drug ingredients and any excipients if present are dispersed", with propellants being examples of substances encompassed by this phrase, while the accepted meaning is "the absence of **any** inert substance in which or on which the active drug ingredients and any excipients if present are dispersed." According to Applicant's own admission (page 3, lines 5-11), medicaments "may not be readily soluble in this propellant (HFA 227). The specification states that the active drug ingredient of the instant invention is practically insoluble in water, slightly soluble in methanol, ethanol, and isopropanol; soluble in acetone and chloroform, and freely soluble in tetrahydrofuran, but it does not state that

the active is soluble in HFA 227. Therefore, one must conclude that the propellant of the instant invention is encompassed by the term "carrier" and therefore it is unclear how a formulation that is "free of a carrier" may contain a compound that is clearly a carrier. The term is indefinite because the specification does not clearly redefine the term.

Claims 8, 9,19, and 20 recite the limitation "the fine particles" in line 1. There is insufficient antecedent basis for this limitation in the claim.

The remaining claims are rejected as being dependent upon a rejected claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fassberg et al. (U.S. Patent No. 5,474,759).

Applicant's claims are drawn to metered dose inhalers containing a composition comprising an aerosol suspension formulation comprising mometasone furoate, a surfactant, and HFA 227, also known as 1,1,1,2,3,3,3-heptafluoropropane, wherein the formulation is free of a carrier (claim1). Claims 2-5 further limit claim 1 by requiring specific quantities of the active agent: about 50 μg to about 400 μg (claim 2), about 100 μg (claim 3), about 200 μg (claim 4), about 400 μg (claim 5). Claim 6 requires that the surfactant be selected from a group consisting of lecithin, stearic acid, palmitic acid, magnesium stearate, magnesium palmitate, and magnesium laureate. Claim 7 requires that the formulation is free of additional excipients.

Regarding the limitation of claim 1 requiring the metered dose inhaler to contain a formulation free of a carrier, the Examiner contends that propellants, including HFA 227, are carriers per Applicant's definition, as described above on page 3 of this office action. Therefore the requirement that the formulation be free of a carrier is not given weight for examination purposes.

Fassberg teaches aerosol formulations comprising **1,1,1,2,3,3,3-heptafluoropropane**, a **medicament**, optionally an excipient and optionally a **surfactant** (abstract).

Fassberg teaches several different aerosol formulations wherein excipients are required, **excipients are optional,** and the optional **surfactant** includes soya **lecithin** (column 3, lines 5-67).

Fassberg teaches that the medicament of his invention may include **mometasone furoate** (column 4, line 2 and column 6, lines 13-14).

Fassberg teaches that **suspensions** of the present invention preferably may be prepared by either the pressure filling or cold filling procedures well known in the art. For **metered dose inhalators**, suspensions may be particularly preferred for efficacy and stability considerations (column 6, lines 66-67 and column 7, lines 1-3).

Fassberg teaches several examples of compositions comprising **HFA 227**, **mometasone furoate**, and optionally a **surfactant** (Examples XIX-XXII).

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to place the compositions taught by Fassberg within a metered dose inhaler (MDI) to obtain the claimed products of the instant invention, because Fassberg teaches all of the components of the formulation contained within Applicant's claimed MDI (HFA 227, surfactant, and mometasone furoate) and suggests that suspensions of his formulations are particularly preferred for MDIs. A skilled artisan would be motivated to place Fassberg's aerosol formulations into a MDI, because MDIs are known in the art as containers used to contain and administer aerosols and Fassberg suggested the use of her formulations in such devices. Therefore, a person of ordinary skill in the art at the time of the instant invention would have had a reasonable expectation of successfully obtaining a MDI containing a formulation comprising HFA 227, mometasone furoate, and a surfactant.

Regarding claims 2-5 which specify different quantities of the active agent, they are considered obvious, because the optimization of dosage is routine in the pharmaceutical arts.

Claims 1-6, 8-17, and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dickinson et al. (WO 99/51205) in view of Kaplan et al. (U.S. Patent Application 2002/0076382 A1).

Applicant's Claims 1-6 have been described above. Dependent claims 8 and 9 require that the aerosol suspension formulation contained within an MDI is about 55% to about 85 % (claim 8) or about 65% to about 80% (claim 9) dispensed upon actuation of the MDI as fine particles having a particle size less than 4.7 μm. Independent claim 10 is drawn to a process of producing an aerosol formulation comprising the steps of (a) mixing mometasone with a surfactant, (b) filling said mixture into an MDI canister, (c) crimping said canister with a metering valve, and (d) filling said canister with a non-chlorofluorocarbon based propellant. Dependent claim 11 specifies the surfactant as being chosen from the same group listed in claim 6, described above. Claim 12 requires that the process of claim 10 utilize HFA 227 as the propellant. Claim 13 is a product by process claim and is being treated as a product comprising a metered dose inhaler containing a formulation comprising mometasone furoate, a surfactant, and HFA 227. Dependent claims 14-17 introduce the same dosage limitations of claims 2-5 (described above) into the process of claim 10. Claims 19 and 20 require that the aerosol suspension formulation of claim 13 contained within an MDI is about 55% to about 85 % (claim 19) or about 65% to about 80% (claim 20) dispensed upon actuation of the MDI as fine particles having a particle size less than 4.7 μm.

It is noted that open language is used to describe the formulations contained within the MDIs of claims 1 (i.e. comprising) and therefore these formulations may contain other active agents in addition to those mentioned in the claim.

Dickinson teaches **metered dose inhalers (MDIs)** containing a composition comprising an admixture of two different (1st and 2nd) particulate materials and a propellant (page 4, lines 18-21, lines 16-27 and page 5, lines 19-21).

Dickinson teaches that the first particulate material is a **medicament** (page 12, lines 19-2); the second particulate material may comprise one or more active/inactive agents or a mixture thereof (page 12, lines 21-23), with an example of an appropriate medicament being **mometasone furoate** (page 14, line 26).

Dickinson teaches that the first particulate material has a median aerodynamic diameter preferably within the range of **1 to 5 microns**. This meets the size limitation of 4.7 microns of claims 8, 9, 19, and 20.

Dickinson teaches that the second particulate material may be selected from carbohydrates and their reduced forms, amino acids, polypeptides, and proteins, and from physiologically acceptable derivative forms, salts, solvates thereof (page 13, lines 4-8). Although not explicitly mentioned nor prohibited, it is possible that the 2nd particulate material is a biologically active species, which could include proteinic active agents, such as insulin.

Dickinson teaches that the propellant is preferably selected from chlorofluorocarbons and hydrofluorocarbons, including **HFA 227** (page 15, lines 24-30).

Dickinson state that the dosage requirements for any one medicament will be those conveniently employed in inhalers and provides an example wherein the medicament is salbutamol and a single metered dose comprises **100 µg** of salbutamol (page 15, lines 17-18).

Dickinson teaches that the aerosol suspension formulations may contain any additional appropriate ingredients, including **surfactants** (page 16, lines 10-12).

Dickinson teaches a process of making a metered dose inhaler containing formulations comprising a particulate medicament, a 2nd particulate material, and a propellant comprising the steps of (a) **mixing** the particulate medicament and the 2nd particulate material, (b) **dosing** the resulting mixture of step (a) **into the container of the metered dose inhaler**, (c) **crimping the closure cap into place**, and (d) **adding the propellant** (page 21, lines 24-30).

Dickinson teaches that the metered dose inhalers containing aerosol formulations dispense **about 45 to about 55 % fine particles** (Figure 4 and Figure 5).

Dickinson lacks in the teaching of specific surfactants.

Kaplan teaches formulations of **mometasone** (preferably an ester of mometasone, including **mometasone furoate**) and a bronchodilator for pulmonary administration (paragraph 0012 and 0020).

Kaplan teaches that the formulations of his invention may also contain excipients, including surface-active agents (i.e. **surfactants**) (paragraph 0040).

Kaplan teaches that the carrier in aerosol formulations of his formulation is generally a propellant (paragraph 0060).

Kaplan teaches that the **propellant** used in his aerosol formulations may be selected from chlorofluorocarbons and hydrofluorocarbons, including **HFA 227** (paragraphs 0061 and 0062).

Kaplan teaches that one skilled in the art of aerosol formulations may include one or more excipients, including dispersants (i.e. surfactants) such as **lecithin** (paragraph 0063).

Kaplan teaches a process of making a MDI containing an aerosol formulation by placement of the aerosol formulation components into an empty aerosol container, attaching a valve assembly to the container, **crimping** the valve assembly into place, and **metering the carrier (i.e. a propellant)** under pressure and in liquid form **into the container**.

Kaplan teaches that aerosol formulations of his invention may be administered via pressurized **metered-dose inhalers** (paragraph 0085).

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to place the combine the teachings of Dickinson and Kaplan to obtain metered dose inhalers containing a formulation **comprising** mometasone furoate, HFA 227, and a surfactant. A skilled artisan would be motivated to combine the teachings of Dickinson and Kaplan because both teach formulations comprising mometasone furoate, HFA 227, and surfactant. A person of ordinary skill in the art at the time of the instant invention would also have been motivated to combine the teachings of Dickinson and Kaplan because both teach methods of making a metered dose inhaler containing the formulations described above. One of ordinary skill in the art would have had a reasonable expectation of successfully using mometasone furoate, HFA 227, and a surfactant as an aerosol formulation in a metered dose inhaler, because these formulations are known in the art as being amenable to administration from MDIs. Furthermore, Dickinson's teachings would have motivated a skilled artisan to use formulations free of other excipients, because Dickinson provides examples of aerosol formulations in which surfactants and other excipients are **optional** (i.e. not required).

Regarding the variation of mometasone furoate dosages present in the MDI (claims 2-5) and in the process of making MDIs containing said medicament (claims 14-17), these would have been obtained by one of ordinary skill as the result of the routine optimization of dosages practiced in the art.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 7, and 13-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 5,474,759. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are overlapping in the scope of the aerosol formulations contained within the MDIs of the instant invention and the dependent claims have the same or obvious similar limitations.

Independent claim 1 of the instant application is drawn to metered dose inhalers containing a composition **comprising** an aerosol suspension formulation **comprising** mometasone furoate, a surfactant, and HFA 227, also known as 1,1,1,2,3,3,3-

heptafluoropropane. No weight is given to the limitation of claim 1 that the aerosol formulation is free of a carrier.

Independent claims 1, 8, and 9 of U.S. Patent No. 5,474,759 (U.S.P.N. '759) are drawn o aerosol formulations consisting essentially of a medicament, including **mometasone furoate** (claims 8 and 9), **HFA 227**, optionally excipients and/or **surfactants**. Mometasone furoate is a medicament.

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to place an aerosol formulation within a metered dose inhaler (MDI), because it is well known in the art to administer aerosol formulations using inhalers, especially MDIs. Therefore, a skilled artisan would have been motivated to make said MDIs containing the aerosol formulations of U.S.P.N. '759 and would have had a reasonable expectation of successfully obtaining MDIs containing said formulations. Regarding the limitations of claims 2-5 and 14-17 of the instant application, these are met by claims 4-7 of U.S.P.N. '759. Claims 14-17 are based upon the product by process of claim 13 and are treated as a product because the process does not impart any structural limitations to said product. The products of claims 13-17 comprise a MDI containing an aerosol formulation comprising mometasone furoate, a surfactant, and HFA 227.

Claims 1, 2-5, and 13-17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 10, and 12 of copending Application No. 10/967,719 (copending '719) in view of Kaplan et al. (U.S. Patent Application US2002/0076382).

Independent claim 1, dependent claims 2-5, and dependent claims 13-17 of the instant invention have been described above.

Independent claim 1 of copending '719 is drawn to a MDI having a metering valve containing an aerosol suspension formulation comprising a compound selected from the group consisting of mometasone furoate, **mometasone furoate** monohydrate, formoterol, formoterol fumarate, and/or a combination of any one of the same; a suspension medium selected from the group consisting of **1,1,1,2,3,3,3-heptafluoropropane**, 1,1,1,2-tetrafluoroethane; and a solvent that is ethanol.

The invention of the instant application lacks the explicit teaching of a MDI containing an aerosol suspension formulation comprising a compound selected from the group consisting of mometasone furoate, mometasone furoate monohydrate, formoterol, formoterol fumarate, and/or a combination of any one of the same.

The teachings of Kaplan have been set forth above (see the relevant 103 rejection), however several of his teachings relevant to this ODP rejection are restated herein below.

Kaplan teaches formulations of **mometasone** (preferably an ester of mometasone, including **mometasone furoate**) and a bronchodilator, including **formoterol** for pulmonary administration (paragraphs 0012, 0020, 0045, and 0047).

Kaplan teaches that aerosol formulations of his invention may be administered via pressurized **metered-dose inhalers** (paragraph 0085).

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the teachings of the instant application with those of Kaplan to obtain the metered dose inhalers of copending application '719 containing mometasone furoate

and/or formoterol. A skilled artisan would have been motivated to combine the teachings because both Kaplan and the instant application teach MDIs containing aerosol formulations comprising mometasone furoate and formoterol is a known component of aerosol compositions contained within MDIs. Therefore, a person of ordinary skill in the art at the time of the instant invention would have had a reasonable expectation of obtaining said MDIs containing said aerosol formulations. Furthermore, the open claim language of the instant application allows for the aerosol formulations to contain other active and inactive components.

This is a provisional obviousness-type double patenting rejection.

Claims 1, 10, and 13 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 5-7 of copending Application No. 10/649,398 (copending '398). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are overlapping in scope.

Claims 1, 10, and 13 of the instant application have been described above.

Independent claims 1and 5 of copending '398 are drawn to a process of introducing a suspension or solution of mometasone furoate anhydrous into a metered dose inhaler container said container having a valve attached thereto comprising the steps of (a) introducing mometasone furoate anhydrous, a surfactant, and a **chlorofluorocarbon free propellant** into a vessel that is held under pressure to form a suspension or solution; (b) circulating said suspension or solution from the vessel through a line which includes a filling head; (c) bringing said filling head into communication with said MDI container; (d) introducing a quantity of said

suspension or solution into the container from the line through the valve of said MDI container; (e) withdrawing said filling head from said MDI container; and (f) sealing said MDI container. Crimping can be used to seal a container.

Dependent claims 3 and 7 of copending '398 further limit the propellant of claims 1 and 5, respectively, to the group consisting of **HFA 227** and HFA 134a.

Dependent claims 2 and 6 of copending '398 are product by process claims and are treated as MDI products containing an aerosol formulation comprising mometasone furoate anhydrous, a surfactant, and a chlorofluorocarbon free propellant.

It would have been obvious to a person of ordinary skill in the art that the processes of claims 1 and 5 result in the mixing of the aerosol formulations due to the steps of introducing the formulation of copending '398 into a vessel, circulating said formulation, and subsequently introducing said formulation into a MDI container. It would have been obvious also to a skilled artisan at the time of the instant invention that the process of claims 1 and 5 of copending '398 would yield a MDI containing an aerosol formulation comprising mometasone furoate anhydrous, a surfactant, and a chlorofluorocarbon free propellant. It would have been obvious to a person of ordinary skill in the art that in the absence of unexpected results one could substitute mometasone furoate anhydrous for mometasone furoate in an aerosol formulation. One would have been motivated to use the process of copending application '398 in lieu of the process of the instant application because they have similar steps and utilize similar and obvious aerosol formulations. Therefore, a person of ordinary skill in the art at the time of the instant invention would have had a reasonable expectation of success by substituting the process of copending

'398 for the process of making an aerosol formulation of the instant application to obtain the products of said process of making.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Other Matter

The copending application - 10/229,855 - referred to in the Information Disclosure Statement filed on October 14, 2003 was not considered, because said copending application was abandoned on May 3, 2005.

Conclusion

Claims 1-20 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James H. Alstrum-Acevedo, Ph. D.

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER